**FDA-Industry PDUFA V Reauthorization Meeting**
**November 18, 2010, 11:00am-12:00pm**
**Teleconference**

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**Purpose**

To continue discussion of proposals related to human drug review timelines.

**Participants**

| FDA | | Industry | |
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| Patrick Frey | CDER | Hilary Malone | Pfizer |
| John Jenkins | CDER | Sara Radcliffe | BIO |
| Theresa Mullin | CDER | David Wheadon | PhRMA |
| Bob Yetter | CBER | | |

FDA and Industry began the meeting by affirming the context for the discussions of review process enhancements. Industry affirmed that it is interested in more substantive feedback during the application review cycle to better plan for AC meetings, inform planning related to manufacturing scale-up, product launch, follow-on clinical development activities, and to potentially address issues identified in the applications. FDA affirmed that it is interested in having more time to plan and conduct foreign inspections, address new authorities from the FDA Amendments Act (FDAAA) of 2007 such as risk evaluation and mitigation strategies (REMS) of greater complexity, plan for more frequent Advisory Committee (AC) meetings, and address issues that can be resolved in the first cycle to reduce the need for multi-cycle reviews.

To address both the FDA and industry interests, the agency proposed a review model for new molecular entity new drug applications (NME NDAs) and original biologic license applications (BLAs) that would include a commitment for a late phase meeting with the signatory authority present after primary and secondary reviews are complete. All other NDAs and BLAs would be reviewed under the current review model. FDA stated that the late phase meeting would be an opportunity to discuss issues identified during FDA's review, plan for AC meetings, and address potential risk management considerations. FDA noted that discussion could also include other analyses or new data that sponsors may wish to submit to address any identified deficiencies and a decision by FDA on whether to review the additional information in the same review cycle, which might trigger an extension for a major amendment. To facilitate discussions of AC meetings, FDA also proposed to submit the agency's AC meeting background package to sponsors 21 business days prior to the AC meeting. For those applications discussed at AC meetings, the late phase meeting would be scheduled between a sponsor's receipt of the agency's background package and the AC meeting. FDA also stated that it would continue to implement the Good Review Management Principles and Practices (GRMPs) provision for a mid-cycle communication from the project manager to provide sponsors with a status update of the application including timelines for AC meetings and any major deficiencies identified at that point in the review.

To allow time for this additional late phase communication with sponsors, FDA proposed that the review clock would start after the two-month period in which FDA conducts filing and application validation activities. To enable FDA to better plan and conduct pre-approval inspections before scheduled AC meetings, FDA also stated that NME NDAs and original BLAs under this review model must be complete at the time of submission including a comprehensive list of manufacturing facilities so that inspection assignments can be made early in the review process. FDA and Industry discussed including a comprehensive list of clinical investigator sites as well to facilitate FDA's evaluation of data integrity and human subject protection. FDA restated its position that unsolicited amendments would not be reviewed

by the agency, and any solicited major amendments received at any time during review could result in a three month clock extension if FDA decides to review it in the current review cycle.

Under this model, FDA stated that its original proposal for clock extensions for REMS, AC meetings, and foreign site inspections would no longer be needed for these applications; however, a REMS submission could be considered a major amendment. Industry asked whether a major amendment extension would be taken by the agency if the application is submitted with a REMS. FDA stated that this would not automatically extend the clock; however a major amendment extension could be taken if FDA's review determines that the REMS must be revised.

Industry asked how this proposed review model might lead to earlier involvement of the Office of Surveillance and Epidemiology (OSE) during review. FDA stated that OSE is included as part of the review team in applications with issues that relate to their areas of responsibility. In some cases, this occurs later in the review when risk management needs are often identified. FDA noted that comprehensive pre-submission discussions that highlight safety concerns in the application could help identify risk management needs earlier in the review. Industry noted that it is also examining best practices that industry sponsors could adopt that could introduce greater rigor into pre-submission meetings with the agency

The discussion of the late phase meeting proposal will continue at the next meeting.